



National Voluntary Laboratory Accreditation Program



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National Voluntary Laboratory Accreditation Program
(NIST / NVLAP)**

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Why Laboratory Accreditation?

- So you don't have to worry.
 - Confidence - it has been done right
 - Competence - get the right answer
 - Equivalence - get the same answer
 - Independence - nothing else is going on
 - Appropriateness - fit for purpose
 - Repeatability - get the same answer twice
 - Reproducibility - others get same answer

World Trade Organization (WTO)

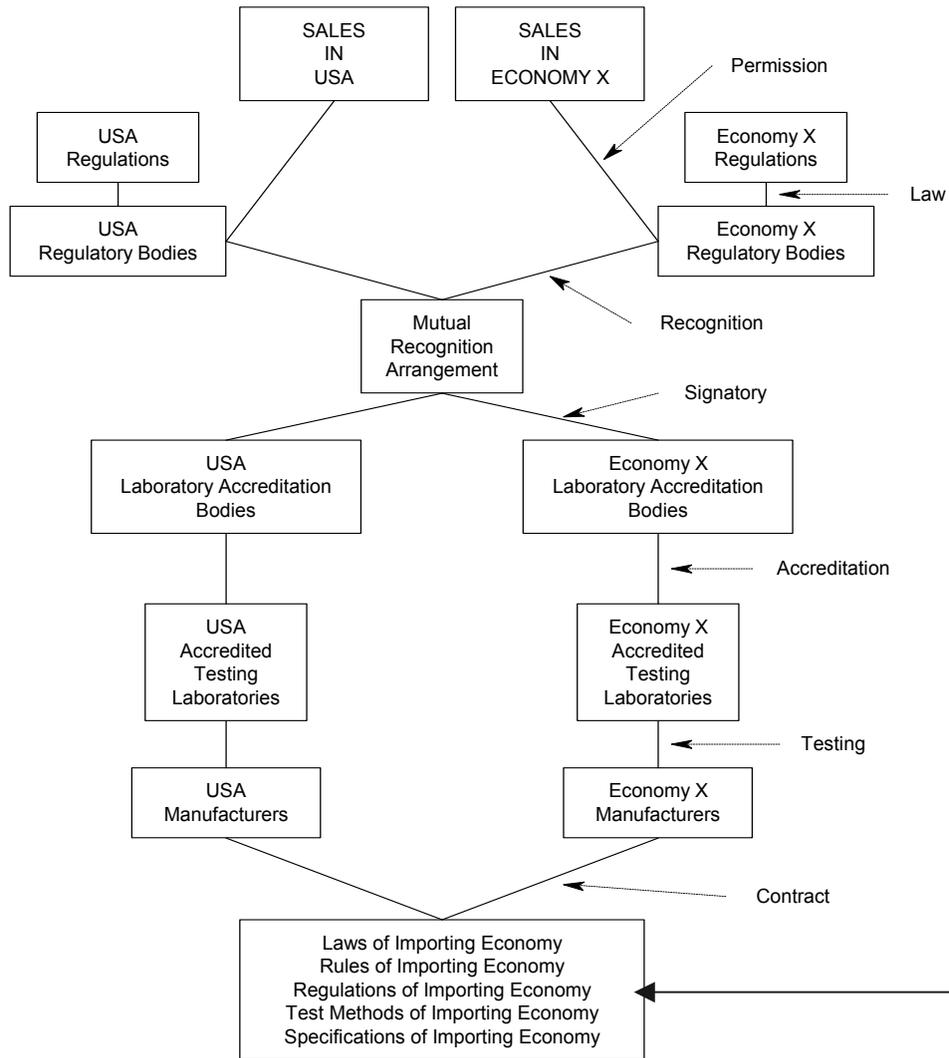
- Final Act - Agreement Establishing the World Trade Organization
- Annex 1 - Multilateral Agreements on Trade in Goods
- Agreement on Technical Barriers to Trade
 - Article 5 - Procedures for Assessment of Conformity by Central Government Bodies
 - Article 6 - Recognition of Conformity Assessment by Central Government Bodies

<http://www.wto.org/wto/legal/finalact.htm>

Mutual Recognition Arrangement (MRA)
For Laboratory Accreditation

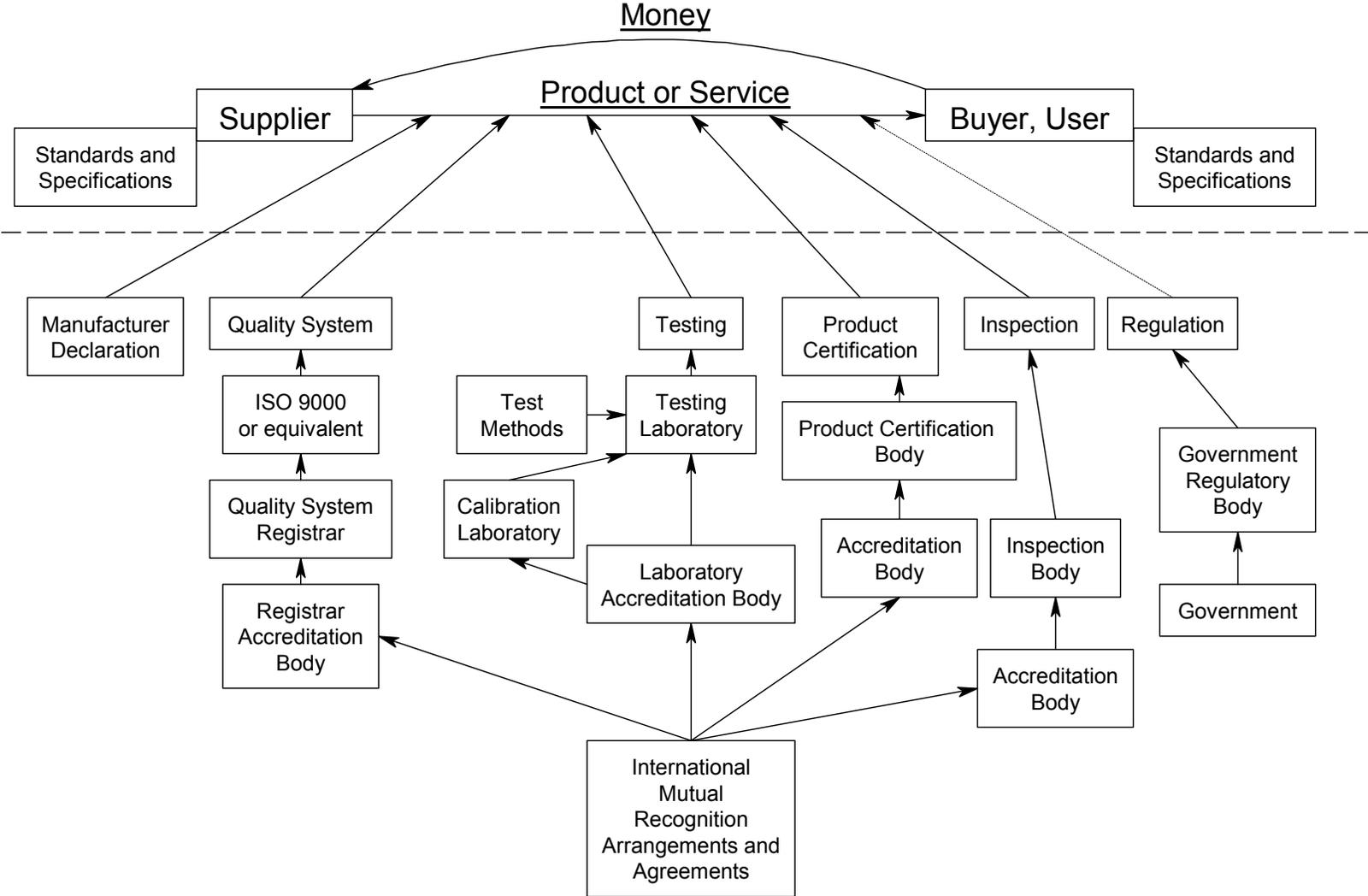
Test Anywhere - Sell Anywhere

Test Anywhere -
Sell Anywhere



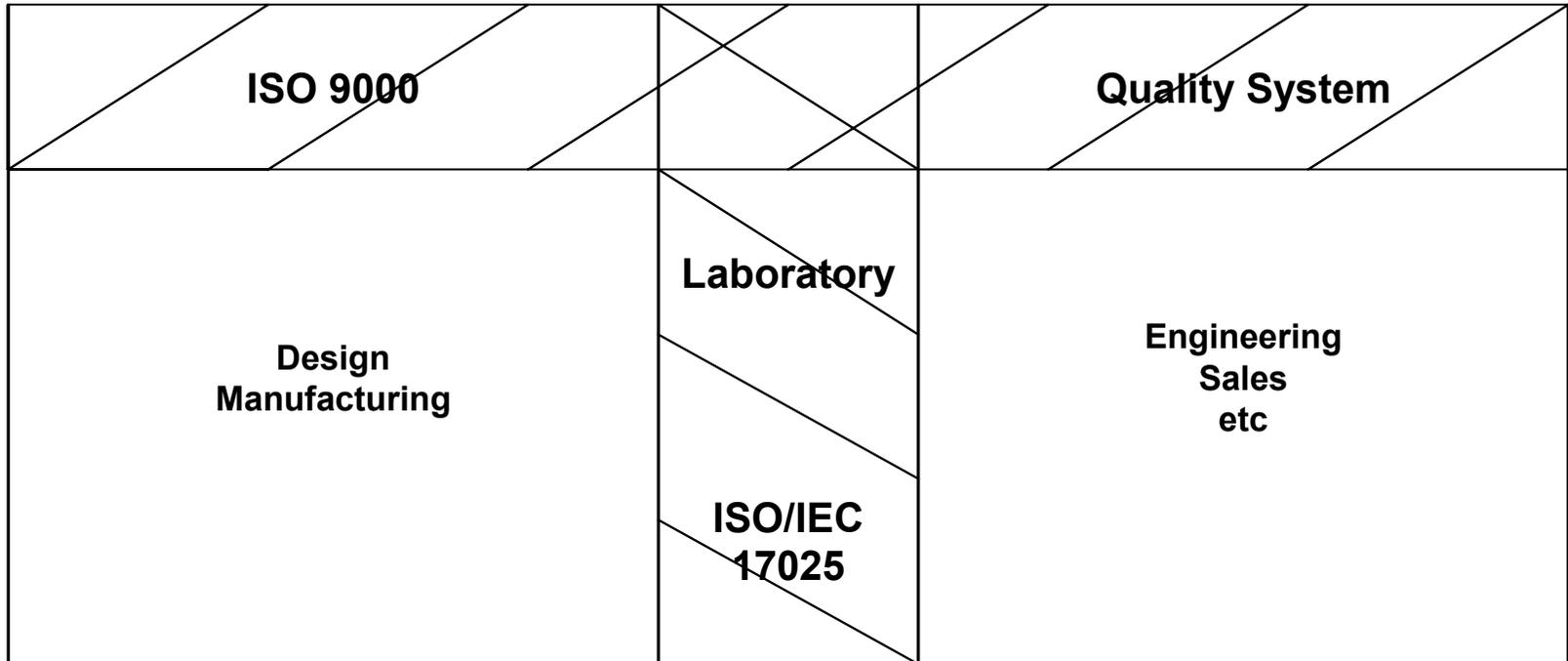
Laws, Rules,
Regulations, Test
Methods,
Specifications of the
IMPORTING
Economy always
apply

DOMESTIC AND INTERNATIONAL TRADE



ISO 9000 and ISO/IEC 17025

ISO 9000 is a stripe across the top of an organization

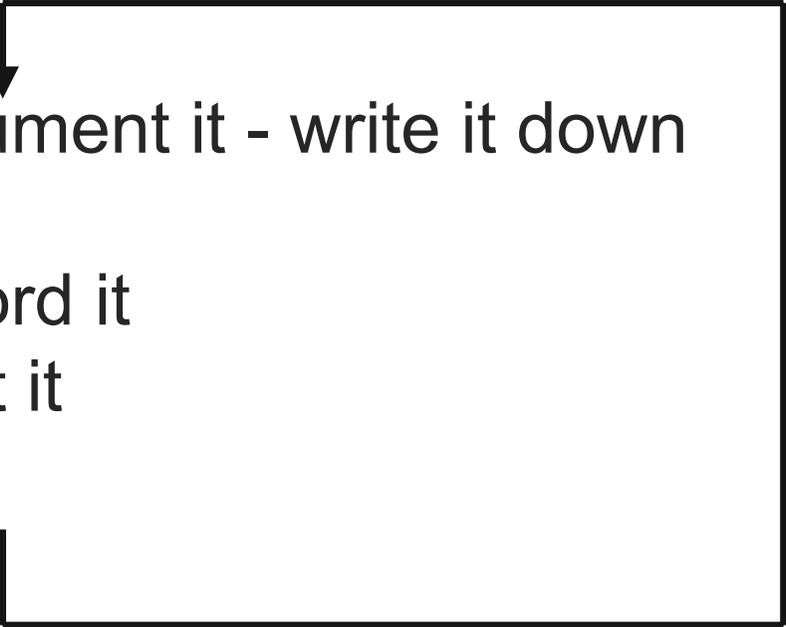


ISO/IEC 17025 is a stripe from top to bottom covering the entire laboratory

Conformity Assessment - ISO Guides and Standards

Testing and Calibration Laboratories 1	Product Certification Bodies 2	Management Systems Registrars - Quality and Environment 3	Inspection Bodies 4	
Recognition Body (ILAC P1, APLAC MR001, EA-2/02)	Recognition Body (No ISO Guides or Standards)	Recognition Body (No ISO Guides or Standards)	Recognition Body (No ISO Guides or Standards)	A
Accreditation Bodies (ISO/IEC Guide 58:1993)	Accreditation Bodies (ISO/IEC Guide 61:1996)	Accreditation Bodies (ISO/IEC Guide 61:1996)	Accreditation Bodies (ISO/IEC TR 17010:1998)	B
Accredited testing and calibration laboratories (ISO 17025:1999 previously ISO/IEC Guide 25)	Product certification Bodies (ISO/IEC Guide 65:1996)	Registrars (ISO/IEC Guide 62:1996, ISO/IEC Guide 66:1999)	Inspection Bodies (ISO 17020:1998)	C
Samples (Test methods and sampling methods)	Products and services (Appropriate product or service standards)	Companies or organizations (ISO 9000, ISO 14000, or equivalent)	Products (Appropriate product standards)	D

Document it



Document it - write it down
Do it
Record it
Audit it
Fix it

CONFIDENCE
IN
INDEPENDENCE and COMPETENCE

International Mutual Recognition Arrangements (MRA)

World MRAs:

- International Laboratory Accreditation Cooperation (ILAC)
for testing and calibration laboratories
<<http://www.ilac.org/>>
- International Accreditation Forum (IAF)
for QMS, EMS, and product certification
<<http://www.iaf.nu>>

International Mutual Recognition Arrangements (MRA)

Regional MRAs:

- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
<<http://www.ianz.govt.nz/aplac/>>
- European co-operation for Accreditation (EA)
<<http://www.european-accreditation.org/>>
- InterAmerican Accreditation Cooperation (IAAC) - MRA in the near future
<<http://www.ibpinetsp.com.br/iaac>>

NVLAP Develops a Program

- Start with NIST Handbook 150
- NVLAP seeks input from *all* sectors of the community including laboratories, developers, vendors, standards writers, regulators, customers, certifiers, the public
- NVLAP publishes the request for a new program in the Federal Register
- Expert advice is sought
- Input is needed both now and later

Program Specific Requirements

- NIST Handbook 150
- NIST Handbook 150-17
Cryptographic Module Testing extends and defines Handbook 150 specifically for this program
- Proficiency Testing is designed specifically for this program
- Technical experts are trained in the NVLAP methodology and to assess to ISO/IEC 17025:1999 (formerly ISO/IEC Guide 25)

Accreditation to ISO/IEC 17025:1999

- Review of quality system: Quality Manual, Procedures, Instructions, Records
- On-site assessment by a team of peer technical experts (who have had ISO 17025 training)
- Participation in proficiency testing
- Evaluation of the above by NVLAP team
- Feedback to the laboratory
- Corrective action by the laboratory

ISO 17025 - Management Requirements (Section 4 of NIST Handbook 150)

- Organization
- Quality system
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints

ISO 17025 - Management Requirements

cont'd

- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

ISO/IEC 17025-Technical Requirements (Section 5 of NIST Handbook 150)

- General - factor contributing to correctness and reliability
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment

ISO/IEC 17025-Technical Requirements cont'd

- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

Additional NVLAP requirements

- Referencing NVLAP accreditation (use of logo and “NVLAP”)
- Implementation of traceability policy
- Approved Signatory
- Authorized Representative(s)

New Applicants for Accreditation

- Send application to NVLAP including:
 - General Application
 - Program Specific Application
 - Fees
 - Quality Manual
- Quality documentation review by assessors
- On-site Assessment with proficiency testing
- NVLAP review and grant of accreditation

NVLAP Fees for domestic laboratories (subject to change)

- First Year - \$8400
 - Admin/Tech, One-time, On-site, PT
- Second Year - \$3300
 - Admin/Tech
- Third Year - \$7900
 - Admin/Tech, On-site, PT
- Fourth Year - \$3300
 - Admin/Tech

Typical On-site Visit - conducted every other year

- Team of two assessors for 1 1/2 days
- Entry meeting with lab management
- Review quality system documentation including, records, personnel folders, technical documentation
- Examine facilities, hardware, software,..
- Staff interviews on all aspects of standards and testing with appropriate demonstrations
- Proficiency testing

Typical On-site Visit - conducted every other year - cont'd

- Exit meeting
 - On-Site Assessment Report given to lab
 - Required written responses to NVLAP are discussed

Quality System documentation includes

- Quality manual
- Policies, objectives, commitments
- Procedures - management and technical
- Instructions - management and technical
- Records - management and technical
- Roles and responsibilities

Proficiency Testing

- An integral part of the accreditation process - customized for field
- A means of periodically checking laboratory performance and ability
- Required for initial and/or continuing accreditation

Proficiency Testing

- Before the on-site visit
 - A written examination is sent to the laboratory
 - The laboratory chooses who works on exam
 - Results returned to NVLAP and reviewed by assessors before on-site visit
 - If the laboratory does not perform satisfactorily, the on-site visit will be delayed

Proficiency Testing

- During the on-site visit
 - Assessors review exam and exam results with staff
 - An artifact is given to the laboratory for testing after the on-site visit. Instructions are discussed. CMVP person will act as a vendor. Artifact is tested by lab while interacting with “vendor” and validation authority.
- After the on-site visit
 - The artifact test is reviewed

Granting Accreditation

- Application
- Review of quality system documentation
- On-site visit with PT
- NVLAP panel to review all information
- All non-compliances must be resolved
- NVLAP grants accreditation for one year

- Renewal each year with on-site every-other year